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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,009	07/23/2001	Baldomero M. Olivera	2314-242	1362

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ROTHWELL, FIGG, ERNST & MANBECK, P.C.  
1425 K STREET, N.W.  
SUITE 800  
WASHINGTON, DC 20005

EXAMINER

BUGAISKY, GABRIELE E

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/12/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/910,009

Applicant(s)

OLIVERA ET AL.

Examiner

Gabriele E. BUGAISKY

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 3-9 and 27-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 10-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of Group I, peptide SF3.2 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that a particular class of conotoxins will share a conserved cysteine framework, disulfide bridging pattern and conserved molecular target. and that there is thus no serious search burden. This is not found persuasive because while it is agreed that that the  $\mu$ - conotoxins share a general 3 dimensional structure and share a similar cysteine framework and disulfide bridging pattern, there indeed is a serious search burden. The Examiner is of necessity limited to the search tools at hand. No generic formula for  $\mu$ - conotoxins has been presented. For search purposes, the Examiner does however, consider , a propeptide along with the mature protein, and, e.g., a modified Trp, to be the same as Trp. Applicant states that while the various conotoxins may be distinct from each other, there is no serious search burden and the scientific literature search While a general word search and search of the subclasses is performed, the Examiner disagrees with the Applicant's position, in that a search for the specific peptides must be made and that a computer search for more than a single specific peptide indeed constitutes a severe burden. The sequence databases are growing at an incredible rate, specific searches for each claimed sequences must be performed and the Examiner is not given unlimited search time and resources The search constitutes AT PRESENT a serious burden. The Examiner can only operate with the search tools currently available to her. The requirement is still deemed proper and is therefore made FINAL.

The requirement is still deemed proper and is therefore made FINAL.

Claims 3-9 and 27-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Information Disclosure Statement***

The listing of references in the specification (pages 89-92) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892 or by Applicants on PTO-1449, they have not been considered.

#### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

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The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

The address change by Gregory Shen has not been initialed.

### *Specification*

Applicants are required under 37 C.F.R. 1.821-1.825 to amend their claims to specific sequences by citing the appropriate SEQ ID Nos. Please note that Xaa2 and Xaa4 of S3.2 in Table 1 are not the 2<sup>nd</sup> and 4<sup>th</sup> amino acids, respectively, of SEQ ID NO: 211; rather, they are aa1 and aa12, respectively. The amendments should reflect the amino acid numbers of the SEQ ID No.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. (e.g., page 2, line 1 and page 5, line 5) Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

### *Claim Objections*

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Claims 1-2 and 10-26 are objected to because of the following informalities: they read upon non-elected subject matter. Claim 1 recites Tables, not SEQ ID Nos:. With respect to dependent claim 2, it is noted that the sequence of the elected peptide does not contain Xaa<sub>5</sub>.

Claims 10 and 24, line 3 of each, and claim 23, line 4, all recite the word "acceptable". This presumably should be "acceptable".

Claim 19, there is no "or" before "phantom limb pain". Also, trigeminal neuralgia, diabetic neuropathy, and post-herpetic pain are not pain, but disorders that cause pain.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are all directed to methods of use; 10-22 are directed to methods of treating disorders associated with voltage gated ion channel disorders,, claim 23 is directed to a method of providing neuromusculoskeletal relaxation, claims and claims 24-26 are directed to a method of alleviating pain. Applicants have obtained a novel conotoxin S3.2 which, like all conotoxins, is presumed to act specifically upon a specific membrane bound channel; however, there is no evidence on the record to show the specificity of this conotoxin; as

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such, the contribution of the specific channel to each of the recited disorders cannot be determined. . As stated by McIntosh (reference 16 of paper # 7) on page 606, final paragraph, "For neurobiologists, the ,major interest in *Conus* peptides is that they are highly subtype-specific ligands. For several ion channel targets, *Conus* peptides are the most specific ligands known. . . This high subtype selectivity is proving to be a general feature of *Conus* peptides"

It is known that specific ion channels are not uniformly expressed throughout the body, but are associated with different tissues, Each set of the above claims is directed to treatment of a different conditions in a greatly different milieu in the body. Thus, it appears that at the time of filing of this application , Applicants had not biochemically characterized the mode of action of S3.2. Without such information, one may not extrapolate which treatment methods would likely be feasible for S3.2. It thus appears premature to claim specific treatment methods using S3.2 without knowing the target of the toxin.

Claims 10-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As stated above, what has not been described cannot be considered enabled..

### ***Conclusion***

No claims are allowed. S3.2 conotoxin and its precursor peptide are deemed free of the prior art.

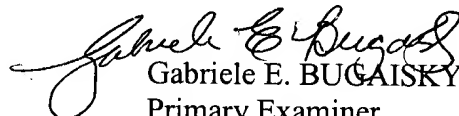
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703)308-

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4201. The examiner can normally be reached on 8:15 AM- 2 PM, Tu & Th, 8:15 AM-1:30 PM, We & Fr.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0196.

  
Gabriele E. BUGAISKY  
Primary Examiner  
Art Unit 1653

March 8, 2003

**GABRIELLE BUGAISKY  
PRIMARY EXAMINER**